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(54) **Administering parenteral fluid**

(57) Parenteral fluid administration apparatus 10 parenteral reservoir chamber 20 enclosed at one end by a piercing pin assembly 22 for attachment to a parenteral solution bag (not shown) and at the other end by a drip forming member 26. Extending into chamber 20 and in fluid communication with member 26 is a fluid passage means 30 in the form of a tubular member 32 having an orifice 33 covered, e.g. with a filter membrane 31. As the fluid level drops in chamber 20, liquid contacts less area of membrane 31 thus affording a slower fluid flow rate until a new solution bag can be provided.

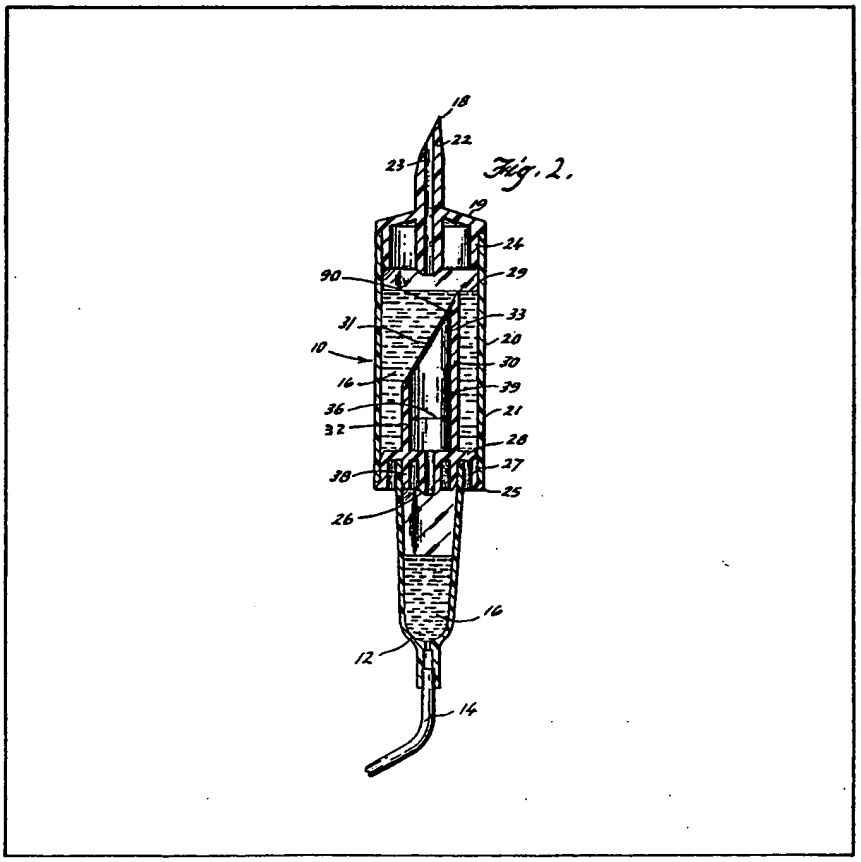

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Fig. 1.

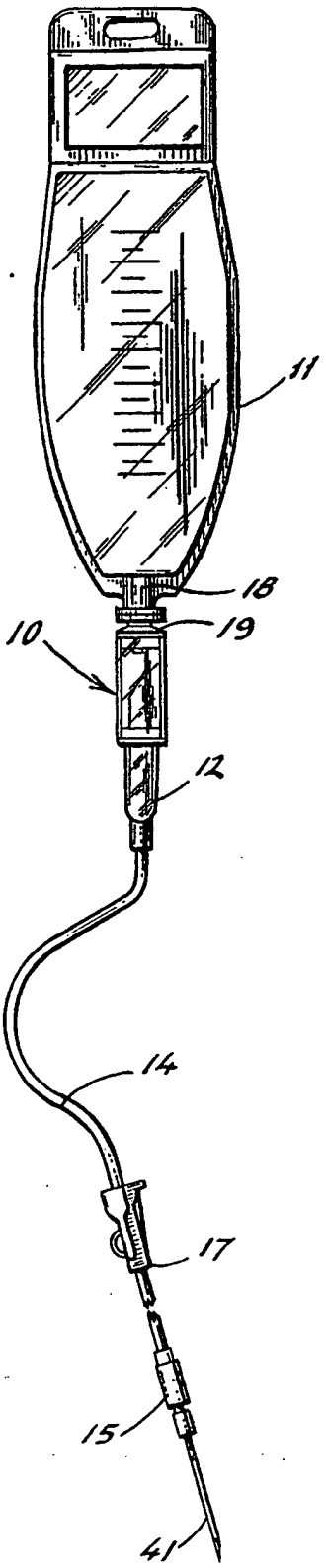


Fig. 2.

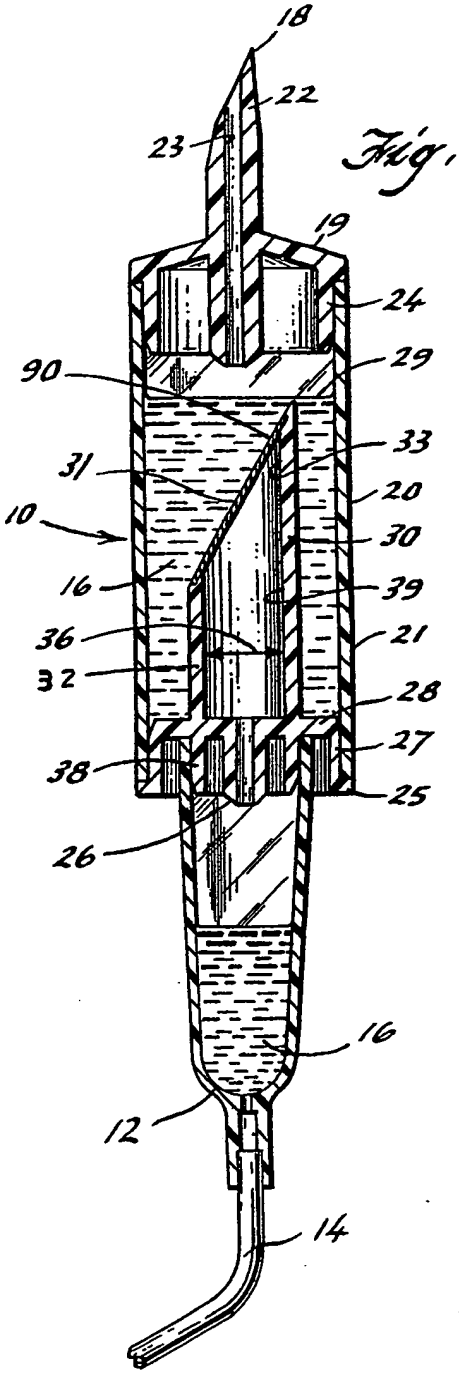
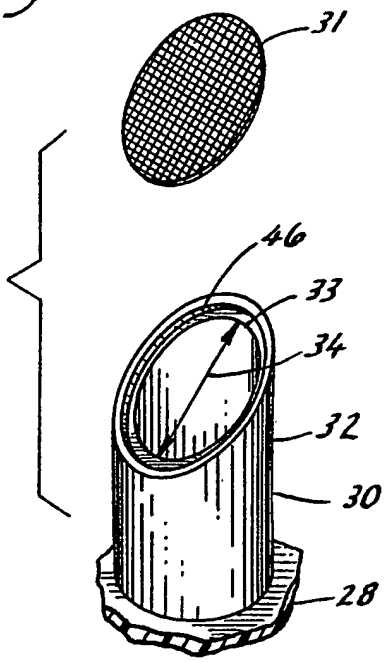


Fig. 3.



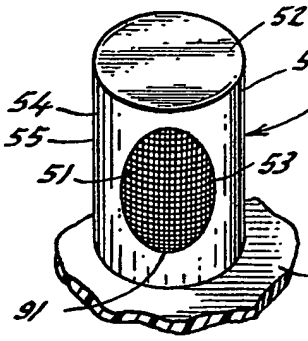


Fig. 4.

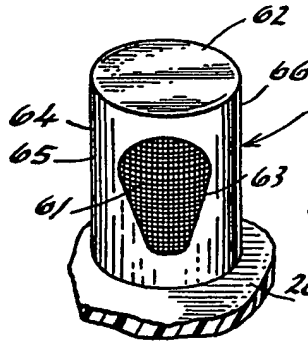


Fig. 5.

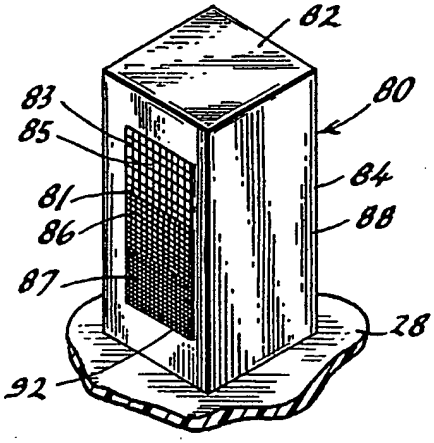


Fig. 7.

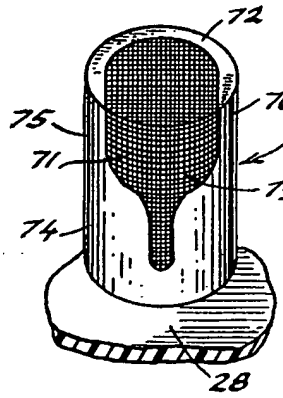


Fig. 6.

SPECIFICATION

Apparatus for controllably administering a parenteral fluid

This invention relates to an apparatus which can controllably administer a parenteral liquid. More particularly, this invention relates to an intravenous administration set which will revert to a different or keep-vein-open (KVO) flow rate when the solution in a container empties.

In the administration of parenteral liquid, the source of parenteral liquid will eventually be exhausted. Unless a constant surveillance is made during the administration, in many instances the source of liquid will become depleted to the patient with the needle in communication with the vein. When this occurs, blood can coagulate around the needle thus effecting a blockage of the end of the needle or the situs where the needle enters the vein. In order to then effect flow when a new solution container is attached, the needle would have to be withdrawn and reinserted at a new site. A unit which is provided to obviate the foregoing adverse effects and to afford a different flow rate in a parenteral liquid is described by Price in U.S. 3,738,361. However, this particular unit requires precise positioning of moving parts which is costly to manufacture and can cause problems during usage. Another device which provides a KVO rate is described in U.S. patent application Serial No. 715,810 filed August 19, 1976 entitled "Apparatus for Controllably Administering A Parenteral Fluid", and is commonly assigned. This particular device utilizes two spaced orifices and some problems have arisen concerning this device in that an abrupt change in flow rate occurs when the top filter or membrane shuts off and the lower smaller area membrane assumes the entire liquid flow during the KVO period.

It is an advantage of the present invention to provide a novel administration apparatus for a parenteral liquid which has a keep-vein-open means. Other advantages are an apparatus for administering I.V. liquids which affords two different flow rates with means which are easy to fabricate and afford positive and reliable functions; an I.V. administration unit which not only can afford different flow rates but can do so without utilizing moving parts; an apparatus which can accomplish a keep-vein-open effect without moving parts and which affords an added advantage of filtering out particulate matter as well as air or gases; a device which in certain embodiments will retain a level of I.V. liquid in the sight chamber and tubing even when the KVO reservoir empties thus avoiding a new venipuncture; and a device which can smoothly convert from a regular to a KVO flow rate.

The foregoing advantages are accomplished and the shortcomings of the prior art overcome by the present apparatus which is comprised of a reservoir chamber having opposing first and second end walls. Connection means for a parenteral liquid container define a fluid flow inlet passageway into the chamber through the first end wall. A fluid flow outlet passageway is in fluid-tight engagement with the second end wall of the chamber. Fluid passage means extend into the chamber in the direction of the first end wall presenting portions proximal and remote therefrom. The fluid passage means is in communication with the fluid flow inlet and outlet passageway. An inlet means in the form of an orifice is provided in the fluid passage means with means operatively associated with the orifice to provide a faster flow rate of parenteral liquid through portions proximate the first end wall of the chamber than portions remote therefrom and to substantially eliminate the flow of air into the orifice. The usual means for administering the liquid to the patient is connected to the fluid flow outlet passageway.

In a preferred embodiment, the means for affording a faster flow rate through portions of the inlet means proximate the first end wall of the reservoir chamber and to substantially eliminate the flow of air into the orifice is an orifice having a T-shaped configuration with the head of the T-shaped portion extending over an end wall of the fluid passage means as well as perpendicularly over the side wall thereof.

A better understanding of the apparatus for administering a parenteral liquid according to this invention will be accomplished by reference to the drawings wherein:

FIGURE 1 is a view in side elevation showing the apparatus of this invention operatively connected to an I.V. solution bag and having interconnected thereto the usual tubing with a hypodermic needle and flow control clamp.

FIGURE 2 is a view in vertical section of the apparatus of this invention showing the reservoir filled to an operative level with liquid and the orifice disposed between the end walls of the reservoir chamber and placed on a bias with respect thereto and a drip chamber integrally secured at the bottom of the reservoir.

FIGURE 3 is a partial detailed view in perspective of the orifice and fluid passage means shown in FIGURE 2 with the filter member removed therefrom.

FIGURES 4, 5, 6 and 7 are views similar to FIGURE 4 illustrating additional embodiments of orifice configurations and filters for the fluid passage means.

Proceeding to a detailed description of one embodiment of the present invention, the controlled I.V. administration apparatus 10 is shown in FIGURE 1 in conjunction with a conventional parenteral solution bag 11 which is described in U.S. Patent 3,915,212. A standard drip or sight chamber 12 is secured to the opposite end of the I.V. administration apparatus and a length of tubing 14 extends from the drip chamber which is ultimately connected to a hypodermic needle assembly 15 with the control of fluid in the tubing being effected by means of an adjustable flow control clamp 17.

As best seen in FIGURE 2, the controlled I.V. administration apparatus 10 is composed of a reservoir chamber 20 having a deformable cylindrical side wall 21. Enclosing one end of the chamber is a piercing pin assembly 22 having a pointed end portion 18. A fluid flow inlet passageway 23 extends through the piercing pin assembly to permit I.V. liquid to flow

into chamber 20. At the opposite end of chamber 20, is a closure 25 having an end wall 28, a reduced diameter section 27 for accommodating wall 21 and also a centrally disposed drip forming member 26. Extending into the reservoir chamber 20 and in fluid communication with drip forming member 26 is fluid passage means 30 in the form of a tubular member 32 having at one end a unitary orifice 33 covered by a filter membrane 31. It will be noted that orifice 33 has a longitudinal axis which extends between end walls 19 and 28 and on a bias or slant with respect thereto.

Referring specifically to FIGURE 3 it will be noted that orifice 33 includes a reduced inner annular section 46 for seating of the filter 31 and securing it thereto such as by means of heat sealing. Alternatively, ultrasonic or epoxy sealing could be used. Preferably, filter 31 is formed from a cellulose acetate material such as produced by the Millipore Filter Corporation located at Bedford, Massachusetts. The filter material is of the hydrophilic type. In the instance of filter 31, it is of .8 micron size and elliptical in configuration.

Extending from closure 25 and secured thereto by means of annular flange 38, is a standard cylindrical drip chamber 12 which has secured at the opposing end a length of flexible plastic tubing 14 for delivery of I.V. liquid 16.

In the following FIGURES 4 – 7, other embodiments of the previously described controlled I.V. administration apparatus 10 are described.

In the embodiment 50 shown in FIGURE 4, the fluid passage means 56 is in the form of a hollow tubular member 54 having a closed end wall 52. Positioned in the side wall 55 and in a circumferential manner is an orifice 53 of a generally elliptical configuration. Covering orifice 53 is a membrane or filter 51 which is of the same configuration as orifice 53 and sealed to the side wall 55 surrounding the orifice in the manner indicated for orifice 33.

The embodiments 60 and 70 shown in FIGURES 5 and 6 are similar to the embodiment 50 of FIGURE 4. Concerning unit 60 it will be seen that membrane 61 is of a tear drop configuration as is orifice 63 in side wall 65. The hollow tubular member 64 provides a fluid passage means 66 through reservoir end wall 28 and is closed by end wall 62 at the opposite end. Unit 70, which is a preferred embodiment, has a generally T-shaped orifice 73 coveredeby a corresponding T-shaped membrane 71. The T-shaped orifice has portions extending over both the end wall 72 and side wall 75 of hollow tubular member 74 with membrane 71 sealed to both the end and side wall. End wall 72 otherwise closes tubular member 74 to provide a fluid passage means 76 through orifice 73.

In the embodiment 80 described in FIGURE 7 the single channel orifice 83 and membrane filter 81 is rectangular in configuration. In place of the hollow tubular members forming the fluid passage means in units 50, 60 and 70, a hollow box-like member 84 provides a fluid passage means 88 and is disposed in fluid communication through reservoir end wall 28 at one end, being closed such as at 82 at the opposite end. Filter 81 is composed of varying bands of mesh sizes with a coarse mesh band 85 at the top, a fine mesh band 87 at the bottom and an intermediate mesh band 86 in between.

Operation

A better understanding of the advantages of the controlled I.V. administration apparatus 10 as well as those described in the other embodiments will be had by description of their operation. As all of the units operate on basically the same principle, only the embodiment referred to as unit 10 will be described with specific comments made for the other embodiments in any manner in which they may differ in their operation.

The controlled I.V. administration apparatus 10 will be packaged separately from a solution container 11. When it is desired to administer the contents of an I.V. liquid 16, such as contained in an I.V. bag 11, the piercing pin 18 will be inserted through the administration port unit 19 to provide fluid communication between the inside of bag 11 and reservoir chamber 20. At this point, the unit 10 will be assembled as shown in FIGURE 1 with bag 11 suitably supported in a vertical position. The reservoir chamber 20 will be primed by squeezing together the flexible side wall 21 as required to fill it so that the fluid passage means 30 and membrane 31 are submerged and the chamber filled to a level 29 of liquid 16 as shown in FIGURE 2. The drip chamber 12 will next be primed by squeezing it wall to wall and held in a squeezed position until the tubing clamp 15 is closed. The force is then released on the drip chamber 12 which action will draw solution through the membrane 31 and prime the drip chamber. The foregoing action can be repeated as needed to fill the drip chamber 12 half full as indicated in FIGURE 2.

After the foregoing priming action, the needle assembly 15 is attached and the air in tubing 14 is expelled by opening the clamp and allowing the set to run. The appropriate venipuncture is made by needle 41 and the set which includes all of the foregoing mentioned components in conjunction with the controlled I.V. administered apparatus 10 is then ready for I.V. administration. Fluid 16 flow rate is established by adjusting the flow clamp 17 until the desired rate of administration is obtained. Liquid will flow through orifice 33 and filter member 31 and will continue to be administered at a given predetermined rate determined by clamp 17 until the solution container empties. When this occurs, the fluid level in the reservoir 20 will drop below the upper level of orifice 33 and membrane 31 as indicated by reference numeral 90. At this point, the controlled I.V. administration apparatus 10 will slowly revert to a keep-vein-open rate which will be a slower one than that accomplished in utilizing both the entire surface area of orifice 33 and membrane 31. Once the level is below the upper level 90, the liquid will flow only through the portion of membrane contacted by the lowering liquid level. It will be apparent that as the liquid level is lowered less liquid will flow through membrane 31. However, as membrane 31 and orifice 33 are placed in an oblique manner with respect to the longitudinal axis of tubular fluid passage means 30, it will take considerable time before the liquid level travels the distance indicated by arrow 34 and

reaches the lowermost portion of orifice 33. This will become even more apparent when considering that flow rates of I.V. solutions range from 5 to 200 ml. per hour with a typical flow rate being 125 ml./hr. The preferred time for liquid to travel the indicated distance would be 1 hour. This slower rate is established so that a constant flow is permitted through drip chamber 12, tubing 14 and into the vein so as to keep a flow maintained until a new solution container or bag 11 can be utilized. In the event a new solution container is not interconnected to set 10 before all liquid empties from chamber 20, a level of liquid will be maintained in sight chamber 12 as filter 31 will afford an air lock. A new venipuncture will not be required because of the hydrostatic pressure. All that is required is to connect a new solution container 11 and reprime reservoir 20 as previously indicated.

The length of time that the KVO rate is delivered after the container 11 empties is dependent on the volume of solution in the reservoir chamber 20 and the rate of flow that the membrane 31 allows liquid to pass.

The KVO rate is independent of the flow rate set by clamp 15 provided the flow clamp is adjusted to a faster rate than the KVO rate. Because of the porosity and hydrophilicity of membrane 31, it will not pass air when the reservoir 20 empties.

The operation of embodiments 50, 60, 70 and 80 will be the same as previously indicated for unit 10 except that the flow through the orifices 53, 63, 73 and 83 as well as the respective filters 51, 61, 71 and 81 may be different from a time standpoint. This is due to the volume of liquid in chamber 20 and the fact that either greater or lesser surface area is contacted by fluid 16 as its level drops in the chamber, when compared to orifice 33 and filter 31. It should be further noted that orifices 53, 63, 73 and 83 are all disposed in a parallel manner with respect to the longitudinal axis of the hollow tubular members 54, 64, 74 and hollow box member 84, except that in the instance of orifice 73 it also has a portion which extends over the end wall of tubular member 74. When compared to the biased orifice 33, the total time for the liquid level to drop below the lowest level of the orifice as indicated by numeral 91 will be faster for the same size and configuration of orifice.

Concerning embodiment 80, membrane 81 offers an additional advantage in having the filter of different mesh size with the degree of coarseness offering more resistance in stages as the liquid level drops. This would afford a slower total flow rate until the level reaches the bottom of orifice 92.

It will be appreciated in all of the units, that the only pathway for the liquid from chamber 20 is through one of the orifices 33, 53, 63, 73 or 83 into hollow fluid passage means 30, 56, 66, 76 and 88, and through end wall 28 by means of hollow drip forming member 26. Once the liquid level drops below the lower portion of the orifice such as shown at 91 and 92 no more liquid will flow through tubing 14.

It will be obvious that orifices 53, 63, 73 and 83 need not be disposed in a parallel manner with respect to fluid flow or 90 degrees with respect to end walls 19 and 28. They could be placed in a slanted or biased manner as indicated for orifice 33. The angle degree for the orifices can vary from 0 (parallel to the housing axis) to any angle less than 90 degrees.

In the foregoing description the inlet means has been described as a single continuous orifice. If desired, the inlet or orifice means could be in the form of a series of continuous apertures with the filter membrane placed thereover. In this manner the wall portions surrounding the apertures would serve as backing support for the filter.

A distinct advantage of the single inlet means for the purpose of effecting a prolonged flow rate is that an abrupt change in flow rate is not brought about with an interruption of flow as the liquid level drops across the orifice. This abrupt change has been noted in those units for effecting a KVO rate when employing two separate orifices. By employing a single orifice the transition from a faster to a slower rate is more gradually effected. Another advantage of the present units is the use of a filter membrane which can be hydrophilic to prevent the passage of air into the fluid passage means and the tubing 14.

The foregoing described units are all disposable with the reservoir chamber formed from a clear flexible plastic cellulose propionate material. The cylindrical walls are solvent sealed to the piercing pin assemblies as well as to the end closures. The same technique is employed in securing the drip chamber to the annular flanges in the outlet closure. The filters are secured to the fluid passage means by a heat seal with the fluid passage means or hollow housing being of a rigid ABS (acrylonitrile / butadiene / styrene) material. Obviously, other plastic materials could be employed which are inert to I.V. liquids and in the instance of the side wall 21 it could be composed of glass although this would pose a slightly more difficult problem in priming the system. While cellulose acetate is the preferred material for composing the filters, other filtering materials of the cellulose family or derivatives of the cellulose family such as cellulose nitrate, cellulose triacetate, mixed esters of cellulose or regenerated cellulose could be employed with the provision that they be hydrophilic with a maximum pore size of less than 10 micrometers. Filters made from vinyls, copolymers of vinyls and polycarbonate could also be used.

It will thus be seen that through the present invention there is provided a controlled I.V. administration apparatus which is simple in its construction yet will allow for a gradually reduced but continuous flow rate of fluid automatically after a fluid level drops below a predetermined level. Except for vertical placement, no special orientation is required. The membranes offer added advantages in that a filtering of any particulate material is effected, the elimination of any flow of gas into the system and elimination of a new venipuncture even when the liquid in the reservoir chamber is completely exhausted. The administration apparatus of this invention can be composed of inexpensive materials and thus is disposable. Automatic reversion from a faster flow rate to a slower flow rate is accomplished without supervision of the units, a source of external power or an

interruption of flow.

CLAIMS

1. An apparatus for administering a parenteral liquid from a parenteral liquid container to the patient comprising:

a reservoir chamber including opposing first and second end walls;

connection means for said fluid container in fluid-tight engagement with said first end wall of said chamber, said connection means defining a fluid flow inlet passageway into said chamber;

a fluid flow outlet passageway in fluid-tight engagement with said second end wall of said chamber;

a fluid passage means extending into said chamber in the direction of said first end wall presenting portions proximal and remote therefrom, said fluid passage means in communication with said fluid flow inlet and outlet passageways;

inlet means in communication with said fluid passage means;

means operatively associated with said inlet means to provide a flow rate of said parenteral liquid through said inlet means at a faster rate through portions proximate to said first end wall than portions remote therefrom and to substantially eliminate the flow of air into said inlet means; and

means operatively associated with said outlet passageway for administering said liquid.

2. The apparatus as defined in Claim 1 wherein said connection means defining said fluid flow inlet passageway comprises a hollow piercing pin.

3. The apparatus as defined in Claim 2 wherein said means for administering said liquid associated with said outlet passageway includes a drip forming member and said apparatus further includes a flexible drip chamber surrounding said drip forming member.

4. The apparatus as defined in Claim 1 wherein said means to substantially eliminate the flow of air into said inlet means is filter means and is of the hydrophilic type.

5. The apparatus as defined in Claim 1 wherein said means operatively associated with said inlet means to provide a faster flow rate through portions proximal to said first end wall than portions remote therefrom and to substantially eliminate the flow of air into said inlet means is defined by an orifice having a longitudinal axis with said longitudinal axis extending in a direction between said first and second end walls and a filter member placed over said orifice.

6. The apparatus as defined in Claim 5 wherein said orifice is of a generally elliptical configuration.

7. The apparatus as defined in Claim 5 wherein said orifice is of a generally tear-drop configuration.

8. The apparatus as defined in Claim 5 wherein said fluid passage means is defined by a tubular member with end and side walls and said orifice is of a generally T-shaped configuration with portions extending over both said end and side walls.

9. The apparatus as defined in Claim 5 wherein said orifice is of a generally rectangular configuration.

10. The apparatus as defined in Claim 9 wherein said filter has a varying degree of mesh size ranging from a finer mesh to a more coarse mesh with the more coarse mesh portion arranged proximal to said first end wall and said fine mesh portion arranged remotely therefrom.

11. The apparatus as defined in Claims 6, 7, 8, 9 or 10 wherein said longitudinal axis extends at an angle of 90 degrees with respect to said first and second end walls.

12. The apparatus as defined in Claims 6, 7, 8, 9 or 10 wherein said longitudinal axis extends on a bias with respect to said first and second end walls.

13. A disposable apparatus for administering a parenteral liquid from a parenteral liquid container to the patient comprising:

a generally cylindrical reservoir chamber having a longitudinal axis and including first and second end walls;

a tubular connection means for said fluid container in fluid-tight engagement with said first end wall of said chamber, said connection means defining a fluid flow inlet passageway into said chamber;

a tubular outlet passageway in fluid-tight engagement with said second end wall of said chamber;

a stand-pipe member having a longitudinal axis extending into said reservoir chamber and positioned with said longitudinal axis generally parallel with the longitudinal axis of said chamber;

an orifice means defined in said stand-pipe, said orifice constructed and arranged to extend from a portion of said stand-pipe remote from said second wall to a portion proximal thereto and to provide a faster flow rate through the remote portions than the proximal portions and to substantially eliminate the flow of air therethrough; and

means operatively associated with said outlet passageway for administering said liquid.

14. The apparatus as defined in Claim 13 wherein orifice means is further defined by extending on a bias with respect to the longitudinal axis of said stand-pipe.

15. The apparatus as defined in Claim 14 wherein said orifice means is of a generally elliptical configuration.

16. The apparatus as defined in Claim 13 wherein said orifice means is of a generally tear-drop configuration.

17. The apparatus as defined in Claim 13 wherein said stand-pipe member includes end and side walls and said orifice is of a generally T-shaped configuration with portions extending over both said end and side walls.

18. The apparatus as defined in Claim 13 wherein said orifice means substantially eliminating the flow of air therethrough is defined by a filter.

19. The apparatus as defined in Claim 18 wherein said filter has a varying degree of mesh size varying from a more open section to a more closed section with the more open section arranged remotely from the second end wall.

20. An apparatus for administering a parenteral liquid, substantially as described with reference to the accompanying drawings.

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